UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM April 9, 2002

SUBJ: Response to Comments Contained in Attachment 6 of Syngenta's Comments on "Atrazine. HED's Revised Human Health Risk Assessment for the Reregistration Eligibility Document (RED)"

TO: Kimberly Lowe, Review Manager
Special Review & Reregistration Division 7508C

Catherine Eiden, Risk Assessor
Health Effects Division 7509C

THRU: Kevin Costello, Acting Chief
Environmental Risk Branch 3
Environmental Fate & Effects Division 7507C

FROM: Mary Frankenberry, Statisitician
James Lin, Environmental Engineer
Environmental Fate & Effects Division 7507C

This memorandum is in response to Attachment 6 of Syngenta's Comments on the HED Human Health Risk Assessment for Atrazine and its Chlorotriazine Degradates. EFED scientists have reviewed the data from the following studies whose results were discussed in the comments contained in Attachment 6. Results from these two studies address the assessment of chlorotriazines in ground water:

> Syngenta/Community Water System Ground Water Monitoring Study for Atrazine and Its Major Degradation Products in Multiple States in the United States (MRID 453999-06)
>
> Re-Sampling of Domestic Rural Drinking Water Wells (MRID 455453-04)

In addition, some comments were submitted concerning environmental fate data for atrazine.

Syngenta's Survey of Community Water Systems for Ground Water

Syngenta performed a "synoptic" survey of ground water designed to estimate the 95th percentile

exposure from two strata of Community Water System (CWS) wells: those which had had at least one positive value prior to 1998 (about 3% of wells in the PLEX system), and those with no previously detected values (about 97% of ground water CWSs). Of the original 14,000+ Ground Water (GW) CWSs in the PLEX database, 435 wells had at least one detectable atrazine sample from 1993 through 1998. 204 wells were selected from this first stratum, which served 1.99 million people. Of the remaining 14,115 CWSs serving over 20 million people with no detected samples, 235 CWSs were selected.

The survey was designed with the goal of estimating the 95th percentile of the overall distribution of each stratum of CWS wells with a relative standard error of about 30%. Precision for any of the upper percentiles of the population, such as the 99th %ile (or upper 1%), is less good, with a wider interval around the estimate, and a lower probability of capturing the "true" proportion in any sample. As EFED discussed in previous meetings with Syngenta, HED and SRRD staff, a more desirable and protective goal for OPP is to estimate at least the 99th percentile of the population of wells and people exposed at that level, still a sizeable number of people. At EFED's request Syngenta ran the 99th ile estimates for the distributions of CWSs and of people served. The results were as follows:

Percentile Estimates for Atz. and Metabolites in Groundwater CWSs[1] with Upper 95% Confidence Limit (UCL)

Population of CWSs						
Atrazine "Detects" Stratum				**All CWSs**		
Atrazine		**Atz + Metabolites**	**UCL**	**Atrazine**	**Atz + Metabolites**	**UCL**
99th %ile	**1.53**ppb (93-98)	**1.90**ppb(c4)	#	**0.219**ppb	**0.561ppb**	**1.09ppb**
mean	**0.166**ppb	**0.427**ppb	**0.547**ppb	**0.0303**ppb	**0.120ppb**	**0.128ppb**

Population Served					
Atrazine "Detect's" Stratum			**Overall Population**		
Atrazine	**Atz + Metabolites**	**UCL**	**Atrazine**	**Atz + Metabolites**	**UCL**

[1] Several methods of data estimation were used, depending on the analytical method and the method of handling non-detect's. Individual cells reflect the highest value reported for that estimate, regardless of method.

99th %ile	**0.75**ppb	**1.59**ppb	**1.67**ppb	**1.06**ppb	**0.621ppb**	**1.60ppb**
mean	**0.126**ppb	**0.326**ppb	**0.474**ppb	**0.036**ppb	**0.129ppb**	**0.150ppb**

For the population of CWS wells, the "atrazine detected" stratum had a 99th %ile of 1.90ppb atrazine+metabolites (no upper bound confidence interval was calculated) and a mean of 0.427ppb(u.c.l.=0.547ppb). Estimates for the distribution of people served were slightly lower. This stratum represents the approximately 3% of CWS wells expected to be higher in numbers of detected samples and sample values.

Estimates for the overall distributions of CWS wells and people are lower than those above because the small "detect" stratum is combined with the larger (~97%) stratum expected to contain mostly "non-detect" samples. The 99th %ile and mean population estimates for atrazine+metabolites were 0.621ppb (u.c.l=1.60ppb) and 0.129ppb (u.c.l.= 0.150ppb), respectively. Median sample values were non-detect in both groups except for one positve sample in the "detect" group, which gave the median result as 0.171ppb in the "detect" group only.

The highest sample value found was 10.8 ppb TCT for the "detect" group in a well that was taken out of service to be investigated for point source contamination. The second highest value was 2.34ppb. (Subsequent monitoring at another well in the same CWS as the highest well gave non-detectable residues.) Calculations were done both with and without those values.

Because this is a statistical survey, the one well with the high value of over 10 ppb for total chlorotriazines may represent other wells that can not be dismissed. Even if the well is taken out of service under suspicion of point source contamination, it remains representative of a situation and level that may be occurring in other GW CWSs. The distribution of values that contains this sample differs in the upper percentiles from the estimated distributions without it.

Syngenta did not calculate upper confidence bounds on some of the 99th %ile population estimates where they would extend outside of the sample data. This may be expected to occur in a number of cases, and for this reason and the above considerations the sample maximums were examined.

All sample values were below OPP's DW Levels Of Comparison. While there is still significant uncertainty in estimating the upper percentiles of the "true" population of CWS wells and people served, the fact that detections comprised a small stratum of the population and that a large percentage (nearly 50%) of that stratum was sampled, gives support to the conclusion that exposure to atrazine and its metabolites from GW CWSs is low and limited.

Syngenta's Rural Well Survey and Resampling

In 1992-94 Syngenta did a survey of 1,505 private rural drinking water wells. Designed to

represent a "high exposure" population, the wells were selected from areas of high atrazine use and conditions of suspected vulnerability due to soil conditions and well depth. One sample per well was taken/analyzed. Fourteen of these original 1,505 wells had either atrazine concentrations above the MCL of 3 ppb, or total chlorotriazine levels approaching or above the DWLOC of 12.5 ppb. The maximum sample contained approximately 20 ppb TCT. These 14 wells, and only these, were selected for resampling in 2001. The resampling results showed lower values, wth all atrazine levels <MCL and all 14 TCT levels under the DWLOC of 12.5 ppb. Syngenta claims point source contamination for the original wells with high values and also cites karst conditions at these sites.

At least three of the 14 "resampling" sites sampled new wells, usually on the same property or relatively near the original well sampled, particularly if the original had been taken out of service. While all of these, again, were near the original "high" wells, the new wells represented some of the lowest values in the new sample. Some appeared to be constructed to much lower depths or to be better reinforced.

At other sites the records indicated that atrazine or other herbicides had not been used for varying amounts of time. These sites showed reductions from original levels, although all showed higher levels than those in the "new" wells constructed on other sites, regardless of the levels of the original sample.

Finally, where records had been kept for any sampling done between the original 1992-94 survey and the present one, levels were variable over the years, with some appearing to decline and others both rising and falling. No use records were available for these intermittent years.

One issue regarding the design of the rural well survey that EFED has pointed out previously is that only one sample was taken for each well. In earlier EFED comments and in discussions with SRRD, HED staff, and Syngenta, this issue was identified based on analyses of the ARP groundwater database. A limited scan of PLEX GW CWS data from the 1993 through 1998 period also provides examples of large variability from year to year in the sample data.[2] The data can show significant monthly variations, which clearly demonstrate that only one low detection value for a well can not rule out the possibility of higher values at other times. For this reason it would be interesting to examine any resampling data Syngenta might have from other wells in the original RWSurvey, even if their original result was less than the MCL at the time.

Syngenta states that there is more spatial variation in the data than the temporal variation obvious in the ARP study. This may not always be the case, depending on the spatial and temporal sampling intervals in any given study. OPP would be interested in seeing Syngenta's data and analysis of the NAWQA studies regarding this issue. While it can be a matter of discussion as to which variability is greater in general, it is clear that both contribute to the uncertainty of the estimates, and the best sampling design would take into account some aspects

[2]PLEX data from White Hall, Ill., for example, show 5.3ppb(1993); 1.2ppb(1994); 10.0ppb(1996); and 7.0ppb(1997).

of both spatial and temporal variability. The fact of only one sample per well for the RWS continues to contribute heavily to the uncertainty of any estimates made from these data.

Because the original sample was part of a survey of private rural wells, point source contamination suspected for any well in the survey might reasonably be expected to be occurring at some of the larger number of wells that each of these sampling units represents. Again, whether they are due to spills, misuse, or karst topography, the findings represent actual risks inherent in pesticide use. While it is gratifying that levels in the 14 wells were lower upon resampling, because only these wells were sampled, the possibility of high(er) concentrations in a larger, representative number of rural wells can not be ruled out. It is not clear where Syngenta's estimate of 30 rural wells over the DWLOC of 12.5 ppb derives from.

In addition, because the original Rural Well Survey was a sample of private rural wells, albeit one that was originally skewed for the purpose of providing an upper estimate of exposure, it represents a larger population of rural wells that serves a larger population of people. Syngenta should present the population(s) of people exposed to drinking water from private rural wells as part of its discussion. EFED agrees that this population is different from the population of GW CWSs.

Syngenta Comments on Drinking Water Estimates from Outside Major Use Area

Syngenta has obtained the SDWA data for 10 "minor use" states, representing additional area that brings the total usage area with data up to 99% from 90% (for "major use"). Although they state that the number of CWSs with previous detect's is lower (on a percentage basis) in this use area compared with the same percentage in the major use area, actual levels are not discussed or summarized. OPP would like to see data from these areas of potentially higher-application minor use.

Syngenta Comment on Laboratory Soil Metabolism Half Life

This comment and others concerning atrazine environmental fate data is addressed in several documents of the EFED response. In one exercise EFED performed the PRZM/EXAMS model runs using Syngenta's suggested in-put values and no significant differences were found in the out-puts.